

Attorney Docket No.: J3692(C)
Serial No.: 10/531,155
Filed: September 26, 2005
Confirmation No.: 4686

REMARKS

Claim 13 has been amended to specify that at least 90% of the total conjugated linoleic acid present in the composition is in the form of cis 9, trans 11 and/or trans 10, cis 12 isomers. See the specification at page 8, lines 10 to 14.

Claims 1-4, 7, 8, 10, 12 and 13 stand rejected under 35 U.S.C. 103(a) as unpatentable over Hoppe et al. (US 2003/0180277) in view of Hersh (US 6011067) and Bryce-Smith (US 6288115). This rejection is respectfully traversed.

The Office Action of February 28, 2008 argues that Hoppe discloses the use of conjugated linoleic acid to promote the energy metabolism of the hair root; Hersh is cited as teaching the use of zinc pyrithione (ZnPTO) for the treatment of dandruff and Bryce-Smith as teaching that the zinc salt of conjugated linoleic acid has greater efficacy over conjugated linoleic acid alone stating:

Hoppe teaches combining the CLA formulation with an anti-dandruff agent, Hersh teaches zinc pyrithione which is dissolved and dissociates in aqueous compositions, and salt formation of an acid in neutral pH is well known to an ordinary skill in chemical art [sic]; therefore, the skilled artisan would have had a reasonable expectation of successfully producing a scalp treatment composition comprising zinc salt of CLA by adjusting the pH of the composition of the prior arts. Since Bryce-Smith suggests that zinc salt of CLA overcomes the irritating effects of CLA, the skilled artisan would also have had motivation to make an anti-dandruff composition with reduced irritation.

Contrary to the Office Action's assertion, zinc pyrithione is relatively insoluble in water. See, for example US 6,054,450 at column 1, line 56 to column 2, line 4:

A hair-care composition containing iodopropynyl butylcarbamate and zinc pyrithione, although it is slightly unstable due to low solubility of zinc

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pyrithione in water showed synergistic effects in antibacterial activity against *Pityrosporum ovlae* and thereby dandruff reduction and itch-suppressing effect.

Furthermore, in order to solve the above problem associated with low solubility of zinc pyrithione in water, they studied the mechanism of dissolution of zinc pyrithione in water. Zinc pyrithione has a spherical shape and a particle size of 0.3-10 μm . **And it is substantially insoluble in water (10-20 ppm)**, ethanol (310 ppm) and most common organic solvents such as ethylene glycol, diethyl ether and isopropanol. Accordingly, it has been found difficult to formulate suitable cosmetic compositions containing zinc pyrithione in a dissolved form. Emphasis added.

It does not necessarily follow, as suggested by the Office Action, that the combination of CLA and ZnPTO in an aqueous carrier results in the formation of the zinc salt of CLA. ZnPTO is a coordination complex in which pyridine derived ligands are bound to zinc via oxygen and sulphur atoms; as such it unlike ionizable salts (e.g., ZnSO_4), where zinc ion is theoretically available to form a salt with climbazole. In Example 1 of Bryce-Smith, the zinc salt of CLA was prepared, not from ZnPTO, but by a process that involved heating about 69% of CLA to 70°C with "Emulsifying Ointment BP", and then adding zinc oxide slowly with stirring. Boiling demineralized water was added and the product emulsified by vigorous mechanical agitation to form a product characterized as a white semi-cream.

Applicants further submit that the Office Action has not demonstrated that, in the subject invention, it is a zinc salt of CLA that is responsible for the synergist enhancement in itch reduction afforded by the subject invention. In the testing reported in the subject Examples, a CLA containing lotion was applied an hour prior to washing the hair with the antidandruff (AD) shampoo. Given that the very art cited by the Examiner clearly discloses (and the subject data demonstrates) that CLA in and of itself has an irritating effect on the scalp, it is both surprising and unexpected

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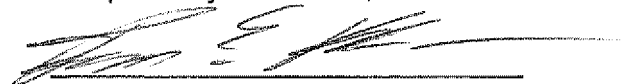
that the treatment with an anti-dandruff agent containing shampoo, one hour after the application of the CLA-containing lotion, would result in reduced scalp itch. Applicants also note that claim 7 expressly reads on a system for treating dandruff wherein, within the system, a first anti-dandruff agent-containing component is kept separate from a second conjugated linoleic acid –containing component, which would seemingly preclude the formation of a zinc-CLA salt.

To summarize, Applicants respectfully submit that the treatment with CLA and an AD agent provides a surprising and synergistic enhancement in itch reduction that would not be predicted based on the performance of either component individually.

In view of the foregoing, reconsideration and allowance of the subject claims is respectfully requested.

If a telephone conversation would be of assistance in advancing the prosecution of the present application, applicants' undersigned attorney invites the Examiner to telephone at the number provided.

Respectfully submitted,



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